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09/613,468	07/10/2000	Morten Sloth Weidner	030307-0220	9245

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EXAMINER	
GOLLAMUDI, SHARMILA S	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 10/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/613,468	WEIDNER, MORTEN SLOTH	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt for Amendments and Remarks filed 7/26/05 is acknowledged. Claims **41-67** are pending in this application. Claims 1-40 stand cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 45 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 45 is directed to a composition that is encapsulated, which is vague and indefinite since it is unclear what the composition is to be encapsulated in. Further clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 52-53, 56-58, 60-62, and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/01126 to Van Amerogen.

WO discloses a method of manufacturing an ester mixture from cinnamic acid esters. See page 6, lines 1-8. The sterol esters that are particularly suitable are those from sheanut (Butyrospermum parkii). See page 5, lines 19-25. The mixture of fatty acid sterols contains 2-

45% alpha-amyrin, 0.2-25% beta-amyrin, 0.2-35% lupeol, 2-45% butyrospermol, 0.1-15% germanicol. See page 10. Note that this ester mixture reads on the broad recitation of "composition" and "concentrate". The mixture is added to food products in the amount of 0.5-40%. The examples disclose mixing 40% ester mixture with various oils (reads on the carrier), to provide a spread. Note that the spread reads on the broad recitation of "an oral dosage form". With regard to claim 62, the spread reads on the composition comprising the extract.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by the amendment of 7/26/05. However, the merits of Van Amerogen will be discussed since it is still applicable as prior art.

Applicant argues that WO discloses only 2-45% alpha-amyrin, 0.2-25% beta-amyrin, 0.2-35% lupeol, 2-45% butyrospermol and the instant invention requires at least 5% alpha-amyrin or beta-amyrin, at least 5% lupeol, and at least 5% butyrospermol. The examiner points out that Van Amerogen's range of amyrin, lupeol, and butyrospermol respectively fully encompass and thus anticipate the instant range.

Claim 52-53, 56-57, and 60-62 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 99/63031 to Alander.

WO 99/63031 discloses a fractionation process wherein the liquid fractions of shea butter have a high content of phytosterols (triterpene alcohols) that are useful for cosmetic, i.e. body lotions and sunscreens and pharmaceutical preparations. See abstract and page 8. WO teaches the triterpene fraction of shea butter contains 40% alpha-amyrin, 6% beta-amyrin, 9% lupeol, 14% butyrospermol, 5% parkeol, 4% taraxasteryl cinnamate, and other components. The triterpene

alcohol fraction is in the amount of 24% (example 5-6), 22% (example 5-6), and 31.7% (example 8) of the entire shea liquid fraction. The fraction also contains the sterols. WO discloses the anti-inflammatory properties of the fractions. See biological tests.

It appears that applicant is not entitled to the priority dates since the provisional does not have support for the instant ranges.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by the amendment of 7/26/05. However, the merits of WO 99/63031 will be discussed since it is still applicable as prior art.

Applicant argues that WO discloses only 16.1% alpha/beta-amyrin, 3.2% lupeol, 5.6% butyrospermol and the instant invention requires at least 5% alpha-amyrin or beta-amyrin, at least 5% lupeol, and at least 5% butyrospermol. Applicant argues that the percentage in the Table are not the total triterpene content of the fraction but the amount of the individual triterpene cinnemates relative to the total amount of triterpene cinnemates. The examiner points out that the Alander's liquid shea butter fraction, the triterpene cinnemate fraction itself reads on the broad recitation "composition" and thus satisfies the required weight percentages. Further, the examiner points out that the applicant is relying on a feature that is not claimed, i.e. applicant has not claimed the amount of the triterpene fraction in the composition. Thus, the claims do not clearly denote what the weight percentages of the amyrin, lupeol, and butyrospermol are relative to, i.e. is the weight percent relative to the entire composition or is the weight percent based on the concentrate used in the composition.

Claims 52-54, 56-58, 60-62, and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Peers (The Non-glyceride Saponifiable of Shea Butter, J. Sci Fd Agric. 1977, 28, 1000-10009).

Peers discloses a shea butter unsaponfiable fraction comprising 1.5% stigmasterol, 1.5% spinasterol, 10.2% beta-amyrin, 26.5% alpha amyrin, 25% butyrospermol, and 21.7% lupeol, among other components. See page 1005. Peers discloses the use of shea butter in chocolate products. See page 1000. The food composition reads on the broad recitation of an "oral dosage form".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 63-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/01126 to Van Amerogen in view Yuan et al (6,190,720).

Van Amerogen discloses a method of manufacturing an ester mixture from cinnamic acid esters. See page 6, lines 1-8 and abstract. The ester mixture has an excellent ability to reduce cholesterol serum levels. See page 3, lines 15-25. The sterol esters that are particularly suitable are those from sheanut (Butyrospermum parkii). See page 5, lines 19-25. The mixture of fatty acid ester of sterol contains 2-45% alpha-amyrin, 0.2-25% beta-amyrin, 0.2-35% lupeol, 2-45% butyrospermol, and 0.1-15% germanicol. See page 10. The mixture is added to food products in the amount of 0.5-40. The examples disclose mixing 40% ester mixture with various oils (reads on the carrier), to provide a spread. With regard to claim 62, the spread reads on the composition comprising the extract.

Van Amerogen teaches the ester mixture in a maximum amount of 40% in a composition, however the reference does not teach using the fatty acid ester of sterol mixture in the instant amount in a composition.

Yuan et al teaches dispersible sterol compositions derived from plants and its use in food such as spreads, dressings, etc. See column 6, lines 20-40. Yuan teaches the sterols lower cholesterol level and can be used in the preparation of dietary supplements (pills) or medicinal compound for those at an increased risk of increased cholesterol. See column 6, lines 50-65 and column 3, lines 1-5. Yuan teaches the use of the sterol component in an amount from 30-90%. See column 4, lines 1-5.

It would have been obvious to one of ordinary skill in the art at the time the invention was made combine the teachings Van Amerogen and Yuan et al and utilize Van Amerogen in the instant amount in a composition. One would have been motivated to do so since Yuan teaches the use of sterols mixtures to reduce cholesterol levels in an amount of 30-90%. Therefore, it

would have been obvious to utilize the Van Amerogen's mixture in the instant concentration in a composition since the prior art clearly teaches that sterols may be utilized in food products or dietary supplements in the instant amount and provide a cholesterol reducing effect. Further, one would have expected success by the instant combination since both reference teach the use of sterol mixtures to reduce cholesterol levels. Thus, a skilled artisan would have been motivated to manipulate the concentration of the ester mixture in a given composition depending on the desired dosage one would want to administer of the sterol ester mixture.

Claims 59 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/01126 to Van Amerogen in view Yuan et al (6,190,720) in further view of Vasquez (5,626,872).

As set forth above, Van Amerogen discloses a method of manufacturing an ester mixture from cinnamic acid esters. See page 6, lines 1-8 and abstract. The ester mixture has an excellent ability to reduce cholesterol serum levels. See page 3, lines 15-25.

As set forth above, Yuan teaches the sterols lower cholesterol level and can be used in the preparation of dietary supplements (pills) or medicinal compound for those at an increased risk of increased cholesterol. See column 6, lines 50-65 and column 3, lines 1-5. Yuan teaches the use of the sterol component in an amount from 30-90%. See column 4, lines 1-5.

The references do not teach the use of capsules.

Vasquez teaches the use of hard capsules and tablets are know to orally administer pharmaceuticals, vitamins, and dietary supplements. However, patients prefer soft capsules since they are easier to swallow than conventional hard capsules and tablets. See column 1, lines 35-45.

It would have been obvious to one of ordinary skill in the art at the time the invention was made combine the teachings Van Amerogen, Yuan et al, and Vasquez and utilize a capsule to administer Van Amerogen's composition. One would have been motivated to do so since Yuan teaches the use of pills to administer sterol compositions as dietary supplement for reducing cholesterol and Vasquez teaches it is known to utilize capsules and tablets for delivering dietary supplements but patient prefer soft capsules since they are easier to swallow. Therefore, a skilled artisan would have been motivated to utilize a soft capsule for consumer appeal.

Claims 41, 45-48, 50-51, 59, and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/63031 to Alander in view of GB 932,662.

As set forth above, WO 99/63031 discloses a fractionation process wherein the liquid fractions of shea butter have a high content of phytosterols (triterpene alcohols) that are useful for cosmetic and pharmaceutical preparations, i.e. body lotions and sunscreens. See abstract and page 8. WO teaches the triterpene fraction of shea butter contains 40% alpha-amyrin, 6% beta-amyrin, 9% lupeol, 14% butyrospermol, 5% parkeol, 4% taraxasteryl cinnamate, and other components. Instant sterols are also taught in the extract. The triterpene alcohol fraction is in the amount of 24% (example 5-6), 22% (example 5-6), and 31.7% (example 8) of the entire shea liquid fraction. The fraction also contains the sterols. WO discloses the anti-inflammatory properties of the fractions. See biological tests.

WO does not specify the use of an oral pharmaceutical composition.

GB 932,662 teaches the therapeutic composition comprising butyrospermol from *Butyrospermum parkii,* especially the triterpene alcohol, which contains beta-amyrin, alpha-

amyrin, and butyrospermol. See page 1, lines 45-50. GB '662 teaches the extract as a bacteriostatic action, has cicatrizing action, and cortisone-like action. See page 2, and page 5. The composition may be topical administered via balms, ointments, etc. for local administration or orally, i.e. tablet form, for systemic administration. See page 5, claim 2.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Alander and GB '662 and utilize an oral form comprising the shea fraction taught in Alander. One would have been motivated to use a oral vehicle comprising the extract with an expectation of success since firstly Alander teaches the extract in a cosmetic or pharmaceutical composition and GB '662 teaches the use *Butyrospermum parkii* triterpene alcohol fractions may be administered using oral vehicles for systemic administration or topical vehicles for local effect. Therefore, one would have been motivated to utilize the instant oral vehicle if one desired to provide systemic anti-inflammatory treatment. Further, the specific use of a capsule is considered obvious to a skilled artisan since GB '662 teaches a solid form oral vehicle and it is known in the art that solid oral forms include capsules and tablets.

Claims 42 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/63031 to Alander in view of GB 932,662 in further view of WO 99/22706.

As set forth above, WO 99/63031 discloses a fractionation process wherein the liquid fractions of shea butter have a high content of phytosterols (triterpene alcohols) that are useful for cosmetic and pharmaceutical preparations, i.e. body lotions and sunscreens. See abstract and page 8. WO teaches the triterpene fraction of shea butter contains 40% alpha-amyrin, 6% beta-amyrin, 9% lupeol, 14% butyrospermol, 5% parkeol, 4% taraxasteryl cinnamate, and other components. The examiner points out that the other components in the composition read on the

broad recitation of "pharmaceutical carrier". The triterpene alcohol fraction is in the amount of 24% (example 5-6), 22% (example 5-6), and 31.7% (example 8) of the entire shea liquid fraction. The fraction also contains the sterols. WO discloses the anti-inflammatory properties of the fractions. See biological tests.

GB '662 teaches the *Butyrospermum parkii* in an oral or topical form.

The references do not specify treating the instant disorders.

WO 99/22706 teaches a cosmetic or dermopharmaceutical composition containing plant extract of Butyrospermum parkii for treating dryness, dermatitis, eczema, sunburns, and burns. See abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize Alander's composition containing shea butter fractions to treat inflammatory conditions such as dermatitis and psoriasis which is characterized by dry, scaly skin. One would have been motivated to do so since WO teaches the active components of the plant extract in Butyrospermum parkii (shea butter) are used for dry skin dermatitis, eczema, sunburns, and burns. Further, one would have expected success since Alander also teaches the anti-inflammatory action of shea butter.

Claims 42-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/63031 to Alander in view of GB 932,662 in further view of Kweifo-Okai et al (Antiarthritic Mechanisms of Amyrin Triterpenes, Research Communications in Molecular Pathology and Pharmacology, Vol. 85, No. 1, July 1994, pp. 45-55).

As set forth above, WO 99/63031 discloses a fractionation process wherein the liquid fractions of shea butter have a high content of phytosterols (triterpene alcohols) that are useful

for cosmetic and pharmaceutical preparations, i.e. body lotions and sunscreens. See abstract and page 8. WO teaches the triterpene fraction of shea butter contains 40% alpha-amyrin, 6% beta-amyrin, 9% lupeol, 14% butyrospermol, 5% parkeol, 4% taraxasteryl cinnamate, and other components. The examiner points out that the other components in the composition read on the broad recitation of "pharmaceutical carrier". The triterpene alcohol fraction is in the amount of 24% (example 5-6), 22% (example 5-6), and 31.7% (example 8) of the entire shea liquid fraction. The fraction also contains the sterols. WO discloses the anti-inflammatory properties of the fractions. See biological tests.

GB '662 teaches the *Butyrospermum parkii* in an oral or topical form.

The references do not specify treating the instant disorders.

Kweifo-Okai teaches triterpenes including alpha amyrin have an antiarthritic effect. See page 45.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize Alander's composition containing shea butter fractions to treat inflammatory conditions such as instant arthritis. One would have been motivated to do so since Kweifo-Okai teaches amyrin (one of the active components of the plant extract in Butyrospermum parkii) has an antiarthritic effect. Further, one would have expected success since also Alander teaches the anti-inflammatory action of shea butter.

Claims 49 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/63031 to Alander in view of GB 932,662 in further view of SU 1181171.

As set forth above, WO 99/63031 discloses a fractionation process wherein the liquid fractions of shea butter have a high content of phytosterols (triterpene alcohols) that are useful

for cosmetic and pharmaceutical preparations, i.e. body lotions and sunscreens. See abstract and page 8. WO teaches the triterpene fraction of shea butter contains 40% alpha-amyrin, 6% beta-amyrin, 9% lupeol, 14% butyrospermol, 5% parkeol, 4% taraxasteryl cinnamate, and other components. The examiner points out that the other components in the composition read on the broad recitation of "pharmaceutical carrier". The triterpene alcohol fraction is in the amount of 24% (example 5-6), 22% (example 5-6), and 31.7% (example 8) of the entire shea liquid fraction. The fraction also contains the sterols. WO discloses the anti-inflammatory properties of the fractions. See biological tests.

As set forth above, GB 932,662 teaches the therapeutic composition comprising butyrospermol from *Butyrospermum parkii,* especially the triterpene alcohol, in an oral dosage form.

The references do not teach the use of Calendula officinalis in the composition.

SU 1181171 teaches the anti-inflammatory properties of the marigold plant and its extract (Note abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to further utilize marigold extract in the composition. One would have been motivated to do so with a reasonable expectation of at least an additive if not a synergistic effect in the composition since Alander teaches the anti-inflammatory activity of the composition and SU 1181171 teaches the anti-inflammatory properties of marigold.

Conclusion

All the claims are rejected at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
Art Unit 1616

SSG

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER